

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/03505	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL03/00771	International filing date (day/month/year) 25 September 2003 (25.09.2003)	Priority date (day/month/year) 25 September 2002 (25.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/32 and US Cl.: 606/167		
Applicant BY-PASS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 22 April 2004 (22.04.2004)	Date of completion of this report 24 November 2004 (24.11.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Bradford C Pantuck Telephone No. (703) 308-0858 <i>Sheila H. Vandy</i> Paralegal Specialist Tech. Center 3700

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-13 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

- ☒ the claims:
pages NONE, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages 14-19, filed with the letter of 06 September 2004 (06.09.2004)

- ☒ the drawings:
pages 1-6, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>8-11,13-19,24,29,34-37,42 and 45-47</u>	YES
	Claims <u>1-7,12,20-23,25-28,30-33,38-41,43 and 44</u>	NO
Inventive Step (IS)	Claims <u>13-19, 24, 29, 34-37,42 and 45-47</u>	YES
	Claims <u>1-12,20-23,25-28,30-33,38-41,43 and 44</u>	NO
Industrial Applicability (IA)	Claims <u>1-47</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-7, 12, 20-23, 25-28, 30-32, and 44 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 6,387,108 B1 to Taylor et al. Regarding Claims 1-7, 12, 20, 21, Column 4, lines 24-31 and Figure 2 detail the invention. The invention is capable of piercing without tearing a wall. Any marking, edge, or difference in material can be considered a marking by which one could judge an incision depth. The instrument can be made in various sizes. Column 4, lines 12-14 describe forming a "precisely measure and substantially linear incision," which reads on "checking on a marking on the cutter to estimate a resulting incision length," as set forth in claim 30, because in order to precisely measure the depth, the user would have to use one of the markings/edges/differences in material on the cutter in order to know how deep/wide the cut was made.

Regarding Claims 22, 23, 25-28, 30-32, and 44, Figure 1A shows and Column 3 line 65-Column 4 line 3 explain such a method of cutting a vessel from the inside out.

Claims 8-11 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 6,387,108 B1 to Taylor et al. Although Taylor does not disclose these specific dimensions, it would be obvious to make a scalpel having such dimensions, as there would be no surprising advantage to having a scalpel with those dimensions as opposed to other dimensions.

Claims 38-41 and 43 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,197,465 to Montgomery. Montgomery's instrument has a gauge and a portion 34 capable of making a mark on a blood vessel. Component 24 is capable of protecting the distal part of the instrument.

Claim 33 lacks novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,292,309 to Van Tassel et al. Figure 2 shows an elongate element with two lumens (which could be called "slots") extending through the instrument. The instrument has a gauge and indices. The gauge is of such a dimension that the device is capable of performing the intended use.

Claims 13-19, 24, 29, 34-37, 42, and 45-47 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the invention.

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CLAIMS

1. Apparatus for forming an incision of a controlled size in a blood vessel, comprising:
a sterile penetration tip which is adapted to pierce a wall of the blood vessel; and
an arcuate section having a cutting edge defined on an inner portion thereof, extending from said penetration tip,
wherein said arcuate section defines at least one incision length marking thereon.
2. Apparatus according to claim 1, wherein said tip is adapted to pierce said wall without tearing.
3. Apparatus according to claim 1, comprising a handle extending from said arcuate section on an opposite end of said arcuate section.
4. Apparatus according to claim 1, wherein said arcuate section defines at least two incision length markings thereon.
5. Apparatus according to claim 1, wherein said arcuate section defines at least two incision length markings, associated with different incision lengths, thereon.
6. Apparatus according to claim 3, wherein said tip, arcuate section and handle lie in a plane.
7. Apparatus according to claim 1, said apparatus includes a cutting edge only on said arcuate section on an inner portion thereof.
8. Apparatus according to claim 1, wherein a non-cutting section is defined between a forward tip of said penetration tip and said cutting edge, said non-cutting section being longer than 0.5 mm.
9. Apparatus according to claim 1, wherein said cutting edge has a linear extent of less than 20 mm.

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10. Apparatus according to claim 1, wherein said cutting edge has a linear extent of less than 10 mm.

11. Apparatus according to claim 1, wherein said cutting edge has a linear extent of less than 5 mm.

12. Apparatus for forming an incision of a controlled size in a blood vessel, comprising:
a sterile penetration tip which is adapted to pierce a wall of the blood vessel;
a body extending from said tip; and
a cutting guide defined on said body.

13. Apparatus according to claim 12, comprising a frame adapted to lock said wall between said frame and said body, from outside the blood vessel.

14. Apparatus according to claim 12, wherein said cutting guide comprises a slot sized to receive a cutting blade suitable for cutting blood vessel walls.

15. Apparatus according to claim 14, wherein said slot is marked with distance markers.

16. Apparatus according to claim 14, wherein said slot has a far end at a point less than 20 mm from said penetration tip.

17. Apparatus according to claim 14, wherein said slot has a far end at a point less than 10 mm from said penetration tip.

18. Apparatus according to claim 13, wherein said frame is attached to said body by a hinge.

19. Apparatus according to claim 13, wherein said frame comprises a cutting stop adjacent said penetration tip and past an end of said cutting guide.

20. Apparatus according to claim 12, wherein said penetration tip is adapted to pierce said blood vessel without causing a tear.

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21. Apparatus according to claim 12, wherein said body is straight.
22. A method of forming an incision in a blood vessel, comprising:
 - (a) inserting a penetration tip into a blood vessel, forming a puncture;
 - (b) fixing said penetration tip so that it maintains a fixed axial position relative to an axis of the blood vessel; and
 - (c) cutting a linear aperture guided by an extension of said penetration tip.
23. A method according to claim 22, wherein fixing comprises penetrating said penetration tip out of said blood vessel.
24. A method according to claim 22, wherein fixing comprises locking said blood vessel to said extension of said tip using a frame on the outside of the blood vessel.
25. A method according to claim 22, comprising, determining an expected incision length prior to said cutting.
26. A method according to claim 25, comprising, removing said fixing if said expected length is not a desired length.
27. A method according to claim 22, comprising, removing said penetration tip and repeating (a)-(b) to achieve a desired expected incision length.
28. A method according to claim 22, wherein cutting comprises retracting said extension to form a cut.
29. A method according to claim 22, wherein cutting comprises guiding a knife along said penetration tip to form a cut.
30. A method of cutting an incision in a blood vessel, comprising:
 - (a) inserting a front tip of a sickle shaped cutter into a blood vessel;
 - (b) manipulating said tip to exit the blood vessel at a different point;

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- (c) checking a marking on the cutter to estimate a resulting incision length; and
- (d) retracting said sickle shaped cutter to cut the blood vessel, following the checking.

31. A method according to claim 30, comprising repositioning said tip prior to said retracting, to exit said blood vessel at a further different point.

32. A method according to claim 30, wherein said blood vessel is only punctured by said tip and is not damaged in any other way by the sickle cutter, prior to (d).

33. An evaluator adapted for evaluating a blood vessel, comprising:
a flat elongate element having a width;
at least two slots of different opening sizes extending through a portion of the width and adapted to receive a blood vessel therein; and
at least one first edge gauge along the element, the edge gauge having a first dimension,

wherein said first dimension is of an incision length in a side vessel suitable for an end-to-side anastomotic connection using an everted blood vessel having the diameter between the two opening sizes.

34. An evaluator according to claim 33 and including at least one third slot extending through a portion of the width, the at least one third slot having an opening of a size greater than the other two slots.

35. An evaluator according to claim 34 and including at least one second gage edge, the edge having a second dimension of an incision length in a side vessel suitable for an end-to-side anastomotic connection using an everted blood vessel having the diameter between the greater size and the two opening sizes.

36. An evaluator according to claim 33 and including a marking section adapted for marking a blood vessel, said marking section being at said end gauge.

37. An evaluator according to claim 36, wherein said marking section is at an edge of said end gauge.

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38. A sterilized marking evaluator adapted for evaluating a blood vessel comprising:
a flat elongate element having a width;
at least one first edge gauge along the element, the edge gauge having a first dimension; and
a marking section adapted for marking a blood vessel, said marking section being at or near said edge gauge.
39. A marking evaluator according to claim 38, wherein said first dimension is smaller than 6 mm.
40. A marking evaluator according to claim 38, wherein said marking section is at an edge of said edge gauge.
41. A marking evaluator according to claim 38, comprising a cap to protect said marking section when not in use.
42. A marking evaluator according to claim 38, comprising a second edge gauge with a second dimension and a second marking section thereat.
43. A marking evaluator according to claim 38, wherein said marking section is near said edge.
44. A method of cutting an aperture in a blood vessel, comprising:
contacting said vessel with a marker having a fixed marking length; and
cutting along said marking.
45. A method according to claim 44, comprising measuring a finished aperture with said marker.
46. A method according to claim 44, comprising inking said fixed marking length prior to said contacting.
47. A method of cutting an aperture in a blood vessel, comprising:

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inserting a penetration tip into a blood vessel at a point;
visually identifying on the blood vessel a desired incision, starting at said point; and
cutting according to said visual guiding.